

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT A****REACTIONS AFTER VACCINATION**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective.

After smallpox vaccination, most people experience normal, typically mild reactions to the vaccine, which indicate that it is beginning to work. Some people may experience more severe reactions that may require medical attention. Consult the "Smallpox Vaccine Information Statement" (VIS), or relevant supplemental fact sheets for information on people who should not be vaccinated at this time.

Following are listings of what you may expect, and conditions that you should be watchful for:

Normal, Typically Mild Reactions

These reactions usually go away without treatment. They can start right away, or they may not start until a week or more after vaccination:

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The glands in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- The vaccinated person may have other symptoms like fatigue, headache, or muscle aches.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.
- The vaccination site may start itching after a few days, this could last until the scab falls off.

Other Things to Expect with Normal Reactions

A recent study found:

- The average size of the pustule (pus-filled blister) at the vaccination site was half an inch.
- The average size of the redness and/or swelling at the vaccination site was 2/3 of an inch.
- Up to 15% of people vaccinated had redness and/or swelling larger than 3 inches, sometimes involving the whole arm. This is usually seen around 7 to 10 days after vaccination.
- Up to 47% of people vaccinated reported pain at the vaccination site, but most said it did not keep them from normal activities.
- About 10% had a fever of 100°F or more. (This can be treated with ibuprofen or acetaminophen.)
- An allergic rash sometimes occurred where the first aid adhesive tape holding the gauze bandage in place touched the vaccine recipient's skin.

If you are concerned about normal reactions:

While these reactions usually go away on their own, if you are concerned about reactions of this type, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

VIS SUPPLEMENT A: Reactions after Vaccination

(continued from previous page)

Symptoms That May Mean You Require Medical Attention

Some people may experience more severe reactions that may require medical attention. You should be aware of symptoms that might indicate you are experiencing such a reaction.

Be watchful for the following symptoms:

- Your vaccine site doesn't look like it is healing normally.
- You develop a rash or sore on other parts of your body.
- You develop a persistent headache (lasting more than 24 hours) or high fever, confusion or seizures.
- You have difficulty staying awake.
- You have difficulty breathing, hoarseness or wheezing.
- You develop hives, paleness, weakness, a fast heartbeat or dizziness.
- You develop an eye infection.
- You develop some other atypical, unexpected problem.

If any of the above occur, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

Serious Reactions That Should Be Evaluated

In the past, about 1,000 people for every 1 million people vaccinated for the first time had reactions that, while not life-threatening, were serious. These reactions may require medical attention:

- A vaccinia rash or outbreak of sores limited to one area (inadvertent inoculation). This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person before washing of hands. It usually occurs on the genitals or face, and can include the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this. **Note: If the eyes are affected, seek immediate attention.**
- A widespread vaccinia rash (generalized vaccinia). The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- An allergic rash in response to the vaccine (erythema multiforme). This can take various forms such as red spots, bumps, or hives.
- Red streaks coming out from the vaccination site are most likely a normal reaction, but could be an infection and should be checked.

Life-Threatening Reactions That Need Immediate Attention

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time had potentially life-threatening reactions, and 1 or 2 died.

These reactions require **immediate** medical attention:

- Serious skin rashes (eczema vaccinatum). This is caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis and can lead to scarring or death.
- Ongoing infection of skin at the vaccination site with tissue destruction (progressive vaccinia or vaccinia necrosum) that can lead to scarring or death.
- Inflammation of the brain (postvaccinal encephalitis) that can lead to disability or death.

VIS SUPPLEMENT A: Reactions after Vaccination

(continued from previous page)

If you believe you are having one of the reactions above:

Call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, call your health care provider, or visit an emergency room.

Treatment for Serious or Life-threatening Reactions

Two treatments may help people who have certain serious reactions to the vaccine: Vaccinia Immune Globulin (VIG) and cidofovir. Neither drug is currently licensed for this purpose, and may have side effects of their own. More information on each will be available at the clinic facility or can be found at the website listed below.

Unsuccessful Vaccination

Around 3% of people may have no reaction from the vaccine. This could mean that vaccination was not successful and you are not protected. In this case, you would need to be vaccinated again.

Note: *Adverse events in the U.S. today may be higher than in the past because there may be more people at risk from immune suppression and eczema or atopic dermatitis. The outcome associated with adverse events may be less severe because of advances in medical care. Rates may be lower for persons previously vaccinated.*

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

(Version 1)

January 16, 2002

Page 3 of 3